

Guidance for Industry and FDA Staff

**Class II Special Controls Guidance:
Shoulder Joint Metal/Polymer/Metal
Nonconstrained or Semi-Constrained
Porous-Coated Uncemented Prosthesis**

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Orthopedics Devices Branch
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Mr. Theodore Stevens at (301) 594-2036 or email trs@cdrh.fda.gov.

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This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Background

On December 17, 1999, FDA issued an order reclassifying the Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis (porous-coated shoulder prosthesis) from class III (premarket approval) into class II (special controls). This document is the special controls guidance for the porous-coated shoulder prosthesis.

FDA has determined that special controls, when combined with the general controls, are sufficient to provide reasonable assurance of the safety and effectiveness of the porous-coated shoulder prosthesis. Thus, a manufacturer who intends to market a device of this generic type must (1) conform with the general controls of the Food, Drug & Cosmetic Act, including the premarket notification (510(k)) requirements described in 21 CFR 807.81, and (2) address the specific risks to health associated with the porous-coated shoulder prosthesis and receive a “substantial equivalence” determination from FDA prior to marketing the device.

This special control guidance document outlines suggested measures that when followed will generally address the risks associated with the porous-coated shoulder prosthesis and lead to a timely 510(k) review and clearance. For the specific content requirements of a 510(k) submission, preparers of submissions should refer to 21 CFR 807.87 and other agency documents on this topic.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be approved/cleared for marketing. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document.

If, however, you believe that information is being requested that is not relevant to the regulatory decision for your pending application or that there is a less burdensome way to address the issues, you should follow the procedures outlined in the “A Suggested Approach to Resolving Least Burdensome Issues” document. It is available on our Center webpage at:

<http://www.fda.gov/cdrh/modact/leastburdensome.html>

Scope

FDA identifies the generic porous-coated shoulder prosthesis as an orthopedic device classified under 21 CFR 888.XXXX (to be determined), product code MBF. It is intended to replace a shoulder joint and achieve biological fixation to bone without the use of bone cement. The device limits, with less than normal anatomic constraints, translation in one or more planes. It has no linkage across the joint.

This generic type of device includes prostheses that have a humeral component made of alloys such as cobalt-chromium-molybdenum (Co-Cr-Mo) and/or titanium-aluminum-vanadium (Ti-6Al-4V) alloys, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, or a combination of an articulating ultra-high molecular weight bearing surface fixed in a metal shell made of alloys such as Co-Cr-Mo and/or Ti-6Al-4V.

The humeral component and glenoid backing have a porous coating made of, in the case of Co-Cr-Mo components, beads of the same alloy or commercially pure titanium powder, and in the case of Ti-6Al-4V components, beads or fibers of commercially pure titanium or Ti-6Al-4V alloy, or commercially pure titanium powder. The porous coating has a volume porosity between 30 and 70 percent, an average pore size between 100 and 1,000 microns, interconnecting porosity, and a porous coating thickness between 500 and 1,500 microns.

Risks to Health

FDA has identified the following four risks to health associated with the use of the porous-coated shoulder prosthesis: (1) infection and fever, (2) adverse tissue reaction, (3) pain and/or loss of function, and (4) revision.

Controls

FDA believes that the guidance documents and applicable recognized consensus standards, identified below, when combined with the general controls, will address the risks associated with this generic type of device and thus provide reasonable assurance of the safety and effectiveness of the device.

Manufacturers should consider complying with the guidance documents and recognized standards that are relevant to their particular device as a means of addressing the risks to health associated with the device.

Manufacturers who reference the recognized standards as part of their 510(k) submission should provide statements regarding conformance or “Declarations of Conformity” under the FDA Modernization Act of 1997. Because statements afford greater flexibility for device developers than “Declarations of Conformity,” submitters of 510(k)s should consider using guidances and standards in this manner.

1. FDA guidance documents:

- a. [“Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement”](#)
- b. [“Guidance Document for Testing Non-articulating, ‘Mechanically Locked’ Modular Implant Components”](#)
- c. [“Draft Guidance Document for the Preparation of Premarket Notification \(510\(k\)\) Applications for Orthopedic Devices-The Basic Elements”](#)
- d. [“Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part I: Evaluation and Testing’](#)
- e. [“510\(k\) Sterility Review Guidance of 2/12/90 \(K90-1\)”](#)

2. American Society for Testing and Materials (ASTM) voluntary consensus standards:

- a. F 67-95, “Standard Specifications for Unalloyed Titanium for Surgical Implant Applications”
- b. F 75-98, “Standard Specification for Cobalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical Implants (UNS R 30075)”
- c. F 136-98, “Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications”
- d. F 648-98, “Standard Specification for Ultra-High Molecular Weight Polyethylene Powder and Fabricated Form for Surgical Implants”
- e. F 1044-95, “Standard Test Method for Shear Testing of Porous Metal Coatings”
- f. F 1147-99, “Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings”
- g. F 1160-98, “Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical Coatings”
- h. F 1377-98a, “Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants UNS R30075”
- i. F 1378-99, “Standard Specification for Shoulder Prostheses”
- j. F 1580-95, “Standard Specification for Titanium and Titanium-6% Aluminum-4% Vanadium Alloy Powders for Coatings of Surgical Implants”

FDA believes that the conformance with the above referenced guidance documents and recognized standards, in addition to the general controls, will be sufficient to control the identified risks to health associated with use of the porous-coated shoulder prosthesis.